

1 MR. JEFFERY: That was a study out of
2 Saskatchewan, I believe, and they looked at all of the
3 population in the province of how many prescriptions
4 were given for antihistamines in different areas, then
5 went back to those people and looked at their driver
6 records. This is an older study that came back in the
7 late '70s or early '80s. They were looking at just not
8 a few hundred, it was a few thousand people involved.

9 DR. GARBER: So, this was a fairly robust
10 study that showed a 1.5 times increased risk for the
11 antihistamines?

12 MR. JEFFERY: Yes. I can give you that
13 citation.

14 DR. GARBER: Okay. And based on the --
15 perhaps you can comment more on Canada. Based on the
16 use of these antihistamines currently in Canada, and
17 again I just want to clarify your previous answer, you
18 feel that that's not a significant risk, even though --
19 even with the potentially large population that's using
20 those medications?

21 MR. JEFFERY: Well, you know, on the scale of
22 one to 100, I mean, antihistamines are at the lower
23 level. If you take a look at the benzodiazepines,
24 which are widely prescribed, also, they're much higher.

1 I mean, yes, it is a significant risk, but it's on the
2 whole level, it's a much lower risk.

3 DR. GARBER: Are the antihistamines available
4 over the counter in Canada as they are here in the
5 United States?

6 MR. JEFFERY: Oh, yes, absolutely.

7 DR. GARBER: Do you have a feel for what the
8 level of those prescriptions are vis a vis
9 benzodiazepines?

10 MR. JEFFERY: Oh, the over-the-counter ones
11 by themselves are used far more widely than the
12 prescription drugs.

13 DR. GARBER: Okay.

14 DR. TEMPLE: The Saskatchewan study captured
15 prescription and non-prescription?

16 MR. JEFFERY: Yes. It was through the whole
17 area of prescription and non-prescription.

18 DR. TEMPLE: And what about Wayne Ray's
19 study? That must have linked to a Medicaid database or
20 something.

21 MS. STEVENS: It did. It was just among
22 people 65 and older. So, the Medicaid enrollees
23 basically got all of their medications through that
24 system, and so --

1 DR. TEMPLE: Including OTC?

2 MS. STEVENS: -- those were captured. Hmm?

3 DR. TEMPLE: Including OTC? So, he would
4 have captured that?

5 MS. STEVENS: He would have captured those,
6 though they could have gotten them, you know, outside
7 of that system. Very few do.

8 DR. GARBER: Just a question for each of the
9 panelists. In an ideal world and recognizing, of
10 course, that we don't live in such a world, how would
11 we go about -- what would give us the data? What
12 specifically would give us the data that we need to
13 make a determination from an epidemiologic standpoint
14 on whether these drugs are problematic in the same way
15 -- in the same sense that, say, alcohol or any other
16 issues are problematic?

17 And then, as a follow-on to that, can we do
18 that? Can we? Do we have the capability of doing
19 that?

20 MR. JEFFERY: Well, I think for alcohol, that
21 was done by the Grand Rapids Study, where they went
22 through and took samples from the public where
23 accidents occurred. It was done over a certain amount
24 of time. That was easy to do with regards to alcohol,

1 and if you want to get the actual role of drugs in
2 driving in the normal population, you would basically
3 have to duplicate the Grand Rapids Study.

4 DR. COUPER: And that probably couldn't be
5 done for most of the drugs because the Grand Rapids
6 Study, I think, was based on breath alcohol levels.
7 So, you weren't being -- it wasn't an invasive blood
8 test or a urine test. So, it was easy to do the breath
9 test, and I doubt that here in America, you'd ever get
10 that number of people. There were thousands of people
11 giving blood samples.

12 DR. GARBER: So, am I correct in interpreting
13 your answers, that it may not be possible to either
14 include or exclude drugs definitively in the way that
15 alcohol was by such a study?

16 MR. JEFFERY: You could do it on a lower
17 extent. There's just a recent study published out of
18 Montreal, from the Forensic Laboratory there, where
19 they took random saliva samples and urine samples from
20 drivers in the known public, and they were looking at
21 about one to two percent of the population that had
22 these drugs on board and whether there were accidents
23 involved and whether they were charged with impaired
24 driving or some type of other offense. So, I mean,

1 it's going to be very, very difficult to do that.

2 DR. GALSON: Okay. I think -- I'm sorry.

3 DR. TEMPLE: What do you think of the
4 following possibility, and, of course, I'm also
5 interested in who you think might be willing to do it;
6 that is, to get blood samples from people -- this
7 sounds bloody, but I'm sorry. People in fatal crashes
8 and compare the blood content of the driver and the
9 passenger as a possible indicator of an increased risk?

10 MR. JEFFERY: Well, that's the study that we
11 actually did in BC. We took blood samples from every
12 one of the fatal motor vehicle accidents, and typically
13 in Canada, I can speak, that that is not routinely
14 done. That is only routinely done whether there's an
15 investigation if they think alcohol or drugs is
16 involved.

17 Alcohol is done on a routine basis. Drugs is
18 only done on one to two percent, and you may get a lot
19 of data involved if you had every fatal motor vehicle
20 driver killed within a certain period of time. If
21 samples were taken from that driver and analyzed, you
22 would get, over a two-or-three-year basis, a good data
23 bank with regards to what drugs are there.

24 I think some of the studies that have been

1 produced already in Australia and my study in BC and
2 the ones in the States and in Europe start to show, I
3 think, the levels of drugs which are already there, and
4 I think we have a good handle on that, but it would
5 give you a far more better understanding of what drugs
6 are involved in driving fatalities.

7 DR. TEMPLE: And perhaps you've already
8 answered this, but do you think there have been enough
9 studies of that type to finger benzodiazepines as a
10 problem? Do you think there is enough data yet on
11 potentially sedating antihistamines to give an answer
12 one way or the other?

13 MR. JEFFERY: Basically, absolutely. I mean,
14 we've got enough data for benzodiazepines. We have
15 enough data now to show that we're not seeing
16 therapeutic levels of sedating antihistamines in fatal
17 motor vehicle accidents or in the impaired driving
18 cases. There are very low levels of less than one
19 percent.

20 MS. STEVENS: I think if we want to look at
21 whether there's an increase in risk, you have to have a
22 comparison group beyond the people who are dying in
23 motor vehicle crashes.

24 DR. TEMPLE: That's why I like the

1 passengers.

2 MS. STEVENS: Well, they're also involved. I
3 think that there's probably more likely a correlation
4 between the driver and the passenger. You need to look
5 at it in the population as a whole.

6 DR. TEMPLE: But before you leave that, that
7 seems logical for alcohol or an abused drug. It
8 doesn't seem equally likely for, say, an antihistamine,
9 does it?

10 MS. STEVENS: Well, if you've got two family
11 members, everyone knows that colds go back and forth,
12 and it's possible, I think there's probably some
13 similarities there that couldn't be written off. So,
14 it might be a long shot.

15 DR. COUPER: If I could make a couple of
16 comments to the last two questions? The first question
17 about the passengers, the study that I mentioned, the
18 culpability study done in Australia by Drummer, and
19 I'll try and get you some references for that, it
20 really was a good study.

21 They did a comprehensive blood test, urine
22 test, vitreous, liver, kidney, a whole lot of samples
23 from the fatalities. It wasn't only from the drivers,
24 it was any passenger in the car or any pedestrian that

1 was hit by a car. So, any road fatalities, they've
2 done that, and they also used a control group as well.
3 So, that could be a nice study for you.

4 Whether -- one of the problems with us
5 toxicologists is a lot of the states have a lot of
6 these data. I know in Washington State, we do
7 comprehensive drug testing on a lot of the fatalities.

8 So, it's not just blood, it's blood and urine. We
9 don't just do alcohol and a drug screen, we go further.

10 We look for the over-the-counter and prescription
11 medications.

12 The problem with the toxicologist is we
13 haven't published these data. So, the data is probably
14 out there in many of the states here and in Canada and
15 probably the rest of the world, but a lot of us just
16 don't publish that results.

17 DR. GALSON: Okay. I think we'll turn now to
18 some audience questions. If we have extra time, we'll
19 go back to the panel again.

20 DR. ELLINGSTAD: Okay. We have four
21 submissions here. One question, I guess it's addressed
22 to NTSB. Would NTSB like to see the DOT establish a
23 regimen for conducting post-accident or other types of
24 testing?

1 I believe the record does show that the NTSB
2 would like the Department of Transportation to do that.
3 We're waiting for them, of course, to respond.

4 We have also a question for Dr. Jeffery.
5 Would you care to speculate on opiate prevalence data
6 in Canada versus the United States related to legal and
7 over-the-counter availability in Canada but not in the
8 U.S.?

9 MR. JEFFERY: Well, in Canada, what we have
10 is Tylenol Number 1, which is eight milligrams, which
11 is over-the-counter. In the data that we see, and the
12 Number 1 drug of abuse abused in BC right now is
13 Tylenol Number 3, which is the 30 milligrams of
14 codeine.

15 In the impaired drivers in the fatal motor
16 vehicle accidents, that is the fourth class of drug we
17 see, and in the narcotic group, codeine far outweighs
18 all of the other narcotics.

19 In Vancouver, we have a huge heroin problem.
20 We don't see that. It's the over-the-counter of
21 codeine tablets and the Tylenol Number 3 which are the
22 major problems for the narcotics.

23 DR. ELLINGSTAD: Any of the other panelists
24 wish to comment on what one would expect in the United

1 States?

2 (No response)

3 DR. ELLINGSTAD: We have another question
4 that I believe was intended for Mr. Allen regarding FAA
5 studies from consecutive four-year periods which showed
6 the incidence of different kinds of drugs in fatal
7 crashes among, I presume, general aviation pilots. Are
8 you familiar with that research?

9 MR. ALLEN: I know of the research. Dr.
10 Tilton or Bob Clarke may be able to -- I don't have the
11 study with me, but it's available, and we'd be glad to
12 give that to whoever.

13 DR. ELLINGSTAD: Okay. If we could have that
14 data or have those studies, the citations for the
15 record?

16 MR. ALLEN: We'll provide them.

17 DR. ELLINGSTAD: If I might add one question?
18 We had -- we've been talking about various kinds of
19 ways of establishing the incidence epidemiologically.
20 Dr. O'Hanlon this morning reminded us of the
21 Borgenstein Grand Rapids Study that basically provided
22 that kind of an indication of incidence with respect to
23 alcohol.

24 Just very quickly, is there any kind of an

1 analog to that with respect to any of the medications
2 we're talking about?

3 MR. JEFFERY: Not that I'm aware of.

4 MS. STEVENS: There's very little with the
5 incidence of medication use in populations. Some of
6 the studies have looked at limited number, but they are
7 either looking at medical prescription records or they
8 ask people, you know, what they've taken which gets
9 into a recall problem.

10 DR. ELLINGSTAD: Is this something that's
11 affected by the comprehensiveness of testing in the
12 various transportation modes or are we testing enough
13 to accomplish that kind of empirical basis?

14 MS. STEVENS: Well, if you're looking to get
15 the information about medication use in the population,
16 you would have to be testing populations, not simply
17 the people who are involved in the fatal crashes. I
18 don't think that that's a practical approach. So, it
19 would be indirect through prescription records and
20 face-to-face interviews would be the way that I would
21 see you'd have to get that information.

22 DR. ELLINGSTAD: Thank you.

23 DR. GALSON: Okay. Nearing the end of this
24 session. Does the Technical Panel have some more

1 points they want to ask?

2 DR. GARBER: I just did want to mention that
3 Mr. Allen mentioned the comprehensive FAA toxicology
4 evaluation that's performed on general aviation --
5 fatally-injured general aviation pilots.

6 The NTSB reviewed those data and uses those
7 -- we use those in our accident investigation
8 evaluation, much in the same way that Mr. Jeffery and
9 Dr. Couper have described for the studies that they
10 have done.

11 In our review of recent data from that, we
12 find that over-the-counter prescription medications to
13 be factors in the accidents more often than we find
14 either alcohol or illicit substances to be factors in
15 those general aviation accidents.

16 I'm curious as to whether (1) that sort of
17 comparison has been done with the data that you have,
18 and (2) whether that surprises any of the panelists,
19 whether that seems consistent with the information that
20 you've seen through the studies that you've either done
21 or reviewed.

22 MS. STEVENS: Well, I wonder if, since we
23 learned to drive at an early age and we drive for so
24 long, if driving as a skill isn't quite different from

1 the skill that's needed as a pilot, and so that we
2 could compensate for a lot of impairments with our
3 driving that may not be possible when flying a plane.

4 DR. GARBER: Any comments from any of the
5 other panelists?

6 MR. JEFFERY: Well, typically what we're
7 seeing in the impaired drivers in the fatal motor
8 vehicle accidents, we're really not seeing just the
9 therapeutic levels. We're seeing high and above those
10 or in the central nervous system depressants, we see
11 the impairment or the fatal motor vehicle accident
12 early on when they've been taking the drug and
13 tolerance hasn't been developed at that time.

14 MR. ALLEN: Within the FRA program, as you
15 know, Dr. Garber, we share with the NTSB any specimens
16 that we have from fatalities, and we have, to my
17 knowledge, never received anything back from the NTSB
18 giving us any data that would make us be concerned
19 about the other drugs and over-the-counter.

20 DR. GARBER: I'm sorry. Does that database
21 include the Florida accident? That's one where the
22 NTSB did find evidence of medication use.

23 MR. ALLEN: I don't know that off the top of
24 my head. I don't know if it was one of the ones that

1 met our criteria.

2 DR. TEMPLE: This probably is a question
3 that's as much for the previous panel as it is for this
4 one, but let me start here and maybe there's some way
5 for them to comment.

6 The various tests of driving function that
7 you heard about earlier show levels of impairment
8 similar to blood levels -- that induced by blood levels
9 of alcohol that everyone agrees apparently is a
10 potential cause of accidents, and at least so far in
11 the epidemiology, however, you don't see anything like
12 that in any of the studies that have been done.

13 Do you have any thoughts about that
14 disconnect or is it a true disconnect? Are there
15 enough data to conclude that there is a disconnect?
16 I'd also be interested in what some of the previous
17 panel thought about that, if there's a way to elicit
18 that.

19 MS. STEVENS: Well, the epidemiology studies
20 that I referred to did not take blood measures. These
21 were doses and use was extrapolated from prescription
22 records, so that it would be an apples and oranges kind
23 of comparison, at least for the studies I was talking
24 about.

1 DR. TEMPLE: Well, but they would be able to
2 see if use of any particular drug was unexpectedly
3 high, and the data we heard earlier in the day are
4 about taking ordinary doses of certain benzodiazepines
5 and sedating antihistamines and finding levels of
6 impairment similar to those that caused trouble when --
7 similar to those -- finding impairment similar to what
8 levels of alcohol that are known to be a problem cause,
9 and yet when -- from the epidemiology the people have
10 described, there doesn't seem to be an association with
11 the use of these agents or not much of one, I guess
12 with benzodiazepines there is, but not at least the
13 antihistamines.

14 Are you saying there's a methodological
15 reason or maybe the driving tests really don't predict
16 that? I mean, I just wondered what your thoughts on
17 this were.

18 MS. STEVENS: I think that getting an
19 estimate of exposure, how much medication people are
20 actually taking through the epidemiologic studies that
21 have been done is very difficult, and there's a lot of
22 possibility of error and not estimating correctly.

23 So, when you have somebody in a laboratory,
24 and you know what you're giving them, that really is

1 different than looking at it in the population and
2 trying to imply from the records how much you think
3 people were taking and when.

4 DR. TEMPLE: I think Dr. O'Hanlon might have
5 an answer to this question.

6 DR. ELLINGSTAD: I think you're going to have
7 to go to a mic. Why don't you come up here to the
8 podium?

9 DR. O'HANLON: We've studied tripolidine,
10 diphenhydramine, chlorpheniramine. Even after 50
11 milligrams of diphenhydramine, we saw impairment one
12 hour later, impairment equivalent to .07. It went down
13 pretty quickly with, as you'd expect, from the
14 pharmacokinetic profile of the drug.

15 We never saw that great a degree of
16 impairment again with another sedating antihistamine.
17 There was some with everyone, but it didn't compare
18 with some of the other antidepressants, some of the
19 mood stabilizers, some of the benzodiazepine hypnotics
20 and anxiolytics we studied.

21 That's why I remarked this morning what's
22 this big deal about antihistamines, except, of course,
23 that the use is so prevalent. There's no discrepancy,
24 at least in our laboratory, the empirical data agrees

1 quite well with the epidemiological data.

2 By the way, a couple of comments I'd like to
3 make. There has been one epidemiology study that shows
4 a relationship between industrial accidents and the use
5 of sedating OTC antihistamines. I think it's by
6 Gilmore, but it's an old man's memory now talking, and
7 you can better find it in my former assistant's
8 excellent article on behavioral toxicity. His name is
9 Jon Ramikers, and he published that in CNS Drugs in
10 1998, I believe. It's a very fine summary of all the
11 epidemiological data published up to that time.

12 So, there has been one indication from
13 epidemiology that sedating antihistamines can do
14 something, and besides that, Ray did not have access to
15 any sedating antihistamine records and said so in his
16 1992 article in the American Journal of Epidemiology.

17 Thank you.

18 DR. TEMPLE: Before you leave, so, you mean
19 his study didn't --

20 DR. O'HANLON: Ray's study did not --

21 DR. TEMPLE: It only included prescriptions
22 which at the time --

23 DR. O'HANLON: -- include sedating
24 antihistamines. Only one antihistamine was available

1 for the prescription at that time, or a couple of older
2 ones, like hydroxyzine, but the main one was
3 terfenadine. That was the main one that showed up in
4 his Medicaid records.

5 DR. TEMPLE: I see. So, you're saying that
6 the failure to find anything is --

7 DR. O'HANLON: In that one case, in that one
8 case, yes.

9 DR. TEMPLE: Okay. And just to be sure I
10 understood what you said before, you don't find most of
11 them having major levels of impairments, --

12 DR. O'HANLON: No.

13 DR. TEMPLE: -- and you're not surprised that
14 nothing much shows up, and even for diphenhydramine,
15 the impairment is relatively short-lived?

16 DR. O'HANLON: .07. I mean, that's not a
17 good thing.

18 DR. TEMPLE: Right. And it doesn't last very
19 long. So, it could depend --

20 DR. O'HANLON: One to three hours,
21 approximately.

22 DR. ELLINGSTAD: We did have a question from
23 the audience that's directed to Mr. Allen, and
24 basically, the question is, how does the DOT feel about

1 NTSB's recommendation that the Department of
2 Transportation make prescription and over-the-counter
3 drugs part of its testing program?

4 MR. ALLEN: Well, it is already part of our
5 rules in that we have rules in each one of our modal
6 policies that address that, and speaking for the FRA,
7 we think that our rules and the testing regimen that we
8 have right now within the FRA covers the basis for the
9 risks that we see out there.

10 I can't really speak for the DOT since, as
11 you mentioned, I think, before, that this is still an
12 open recommendation from the NTSB to the DOT.

13 DR. GALSON: Okay. A few more minutes, if
14 the Technical Panel wants to ask anything else.

15 (No response)

16 DR. GALSON: Okay. Any other questions from
17 the parties?

18 (No response)

19 DR. GALSON: Okay. I think with that, then
20 we'll end this second session and have a 15-minute
21 break, which brings us back here at about 2:32-2:33.

22 (Whereupon, a recess was taken.)

23 DR. ELLINGSTAD: We'll have a little smaller
24 Witness Panel here, and we'll grill them more

1 exhaustively than we have previously.

2 I'd again like to remind both the audience
3 and our party participants to generate your questions
4 and pass them and the parties to get their questions to
5 the moderators. Again, with the smaller panel, we'll
6 be more liberal in terms of the questions that we can
7 entertain.

8 Our third panel consists of representatives
9 from State and Local Government, and we will start out
10 with Mr. William George, Deputy Attorney General from
11 Delaware.

12 Mr. George?

13

14 Witness Panel III - State and Local Government

15 MR. GEORGE: Good afternoon.

16 My name is William George, and I am the
17 Deputy Attorney General for the State of Delaware, and
18 for the last 12 years, I've had the sole responsibility
19 for the prosecution of homicide cases arising from
20 motor vehicle accidents, including commercial vehicles.

21 To address the issues involving the operation
22 of vehicles by those who are drug impaired, I will
23 speak first about the types of laws and regulations
24 that exist at the state level and then about the

1 problems with enforcement of those laws.

2 In Delaware, we rely mainly, if not
3 exclusively, on our DUI, our Driving Under the
4 Influence, statutes as our primary enforcement tool to
5 restrict transportation operators from operating
6 vehicles while impaired by medications.

7 Although geared towards and mainly enforced
8 against those who operate a vehicle while under the
9 influence of alcohol, our statute is broad enough to
10 restrict all drugs, both legal and illegal.

11 Our statute specifically prohibits the
12 driving of a vehicle while under the influence of any
13 drug or under the influence of a combination of alcohol
14 and any drug.

15 However, the enforcement and the prosecution
16 of the drug impaired driver is very difficult on many
17 levels. The first is detection. For over 25 years
18 now, the states, following the initiative of the
19 Federal Government, have been involved in a process of
20 education, of re-education, and of enforcement that has
21 changed our views on alcohol impaired drivers.

22 Our police officers, who are our first line
23 of defense in the detection of the impaired driver, are
24 trained in the detection of alcohol. At our academies,

1 new officers are given the opportunity to watch other
2 officers drink alcohol and then gauge their impairment
3 through the use of standardized field tests and the use
4 of an intoxilyzer.

5 The effects of drug impairment are very
6 subtle, though, and unless the impairment causes the
7 outward and detectable signs usually associated with
8 alcohol impairment, it is possible that the drug
9 impaired driver may go undetected.

10 Even in those cases where signs of impairment
11 are noticeable, where field tests are given, the
12 officer is likely to hit an impasse when the
13 intoxilyzer displays a 00 reading.

14 Specific methods of drug detection and
15 documentation do exist, but they are different from
16 that of alcohol cases, and they are beyond the training
17 and expertise of most police officers today.

18 The second problem is the prosecution of
19 these types of cases. A typical DUI case follows a set
20 pattern during the trial of that case. It begins with
21 the initial observations of the erratic driver by the
22 officer, the stop by the officer, the initial
23 observations of the operator after the stop is made,
24 the establishment of probable cause based on

1 standardized and accepted field tests, and finally the
2 introduction of an intoxilyzer reading or, in rare
3 cases, the introduction of a reading of a blood sample.

4 In a drug impaired case, the intoxilyzer will
5 not provide adequate evidence, and unless the
6 performance on the field test is so poor, it is
7 unlikely that a conviction could be obtained.

8 Even in those cases where a blood sample may
9 have been obtained, the quantitative effects of drugs
10 have not been documented or accepted by our courts to
11 the same degree as alcohol has. Similarly, the urine
12 sample is inadequate and unlikely to be accepted into
13 evidence at all.

14 The detection and prosecution of the drug
15 impaired driver is a problem, but there is a solution.

16 First pioneered by the Los Angeles Police Department
17 with the assistance of NHTSA, the Drug Recognition
18 Evaluation and Classification Program was developed.
19 Its purpose is to determine whether a driver is
20 impaired, and if so, whether the impairment is drug
21 related or medically related and then to determine the
22 broad category of combination of drug categories
23 causing the impairment.

24 The drug recognition expert or DRE is a

1 specially-trained police officer. The officer is
2 trained not only in the testing usually associated with
3 an alcohol case, but also in medical procedures that
4 include an eye examination, HGN testing, and an
5 analysis of the vital signs of the driver.

6 Although the DRE program has now expanded far
7 beyond Los Angeles, it is my opinion that it has not
8 expanded far enough or fast enough to address this
9 problem. Certainly the Federal Government can and
10 should take an active role in expanding the kind of
11 training of police officers. The Federal Government
12 should promote the acceptance of these types of
13 programs through education, just as it has actively
14 promoted education and enforcement of alcohol-related
15 laws.

16 I thank you for your time and attention.

17 DR. ELLINGSTAD: Thank you, Mr. George.

18 Our next panelist is Dr. Jon May with the
19 National Association of Boards of Pharmacy in
20 Gaithersburg, Maryland.

21 DR. MAY: Thank you.

22 I am a consultant to the National Association
23 of Boards of Pharmacy, and I bring you greetings from
24 them. The Executive Director, as I speak, is in

1 Monterey, California, attending the NABP Executive
2 Officer's Conference.

3 In the parlance of the recently-completed
4 World Series, I am a pinch-hitter. I live in
5 Gaithersburg, Maryland. I retired from the U.S. Public
6 Health Service in 1992, having spent 10 years with the
7 Food and Drug Administration.

8 When I talked to Dr. Garber after I was asked
9 by NABP if I was available for this meeting, he told me
10 that we would have about a five-minute time for a
11 statement and that most of our input would come from
12 the questions from the panel and/or the audience.

13 So, I have a statement that has been prepared
14 by NABP. If I read it real slow, it'll reach five
15 minutes. If I read it at my normal talking pace, it
16 will probably take three minutes. So, I will present
17 the statement from NABP, and then we will field
18 questions, although we feel like we're being targeted
19 up here with only two. I came in an hour ago, and
20 there were five people sitting at this table. So, I'm
21 beginning to worry a little bit.

22 Anyway, what we responded to was the question
23 presented by NTSB, and it goes, what types of local
24 requirements serve to restrict transportation operators

1 from operating vehicles under the influence of
2 potentially impairing medications, and how are/can
3 these requirements be enforced?

4 From the State Board of Pharmacy perspective,
5 the scope of direct authority over transportation
6 operators is extremely limited. Pharmacists who fall
7 under the direct authority of the state boards of
8 pharmacy are required to affix warning labels to
9 medication containers dispensed to patients if the
10 medication could affect a person's ability to operate a
11 motor vehicle or heavy machinery.

12 The medications causing the side effects are
13 usually agents which cause drowsiness by impacting the
14 central nervous system. The labeling requirement,
15 although not specifically stated in the State Practice
16 Acts and regulations, is based upon good standards of
17 practice that any pharmacist would use in order to
18 ensure that the patient is safe from harm.

19 State pharmacy boards ensure that these
20 practices are occurring through random inspections and
21 review of documentation for the specific prescriptions.

22 The only other means for regulating and responding to
23 such activities would occur if a patient was injured
24 and formally complained to the state board of pharmacy

1 that they were not adequately warned about the side
2 effects of the medication. In this instance, the
3 pharmacist, not the operator, would fall under the
4 jurisdiction of the state board.

5 Although there is a clear indication to the
6 pharmacist because of his or her knowledge of
7 medications of which medications could have sedating
8 effects, there is no federal mandate from the FDA
9 designating these medications and requiring a specific
10 warning label.

11 Even if this requirement was in effect, NABP
12 is not certain that such a federal mandate would help
13 resolve the problem identified by the NTSB. Although
14 it would place a specific legal mandate on pharmacists
15 to affix the appropriate label, the state boards of
16 pharmacy would not have any authority over operators
17 who actually are prescribed and take the medications.

18 The responsibility for pharmacists to make
19 this warning known to patients is inherently present in
20 good practice standards and could result in
21 disciplinary action against the license of the
22 pharmacist if not followed.

23 NABP is willing to work with the NTSB and FDA
24 to resolve the concerns identified.

1 DR. ELLINGSTAD: Thank you, Dr. May.

2 We'll go for questioning to the Technical
3 Panel. Who wishes to go first? Dr. Garber?

4 Questions from Technical Panel/Parties and Discussion

5 DR. GARBER: And Dr. May, since you spoke
6 last, I'll question you first, if you don't mind, and
7 if there are issues that I touch on, Mr. George, that
8 will -- that have legal implications, I would hope that
9 you would jump in and respond to those as well.

10 In Australia, the pharmacy associations there
11 sort of banded together and got a standardized warning
12 label that they use for a certain list of medications.
13 It's a red warning triangle that sits on the same sort
14 of stickers that are commonly applied in this country.

15 So, what I'd like to ask is, do -- is there
16 any opportunity for pharmacists in this country to do a
17 similar sort of thing, and to what extent do you feel
18 that that might be effective on a voluntary basis?

19 DR. MAY: Well, I read that in the report,
20 and I'll have to ask you a question. I haven't seen
21 it. Is the red triangle simply that?

22 DR. GARBER: Exactly.

23 DR. MAY: Does it have words?

24 DR. GARBER: It's just a warning.

1 DR. MAY: Nothing?

2 DR. GARBER: It's a red warning triangle,
3 which is actually a very common symbol in Australia for
4 danger. It's a road signal that's fairly commonly
5 recognized as meaning dangerous conditions ahead.

6 DR. MAY: Okay. Well, it appears to NABP
7 that there are several problems with that. One, that
8 does not mean that in the United States. In
9 Pennsylvania, on the back of an Amish buggy, it means
10 go slow.

11 I don't think anybody here would recognize
12 it. There would have to be a tremendous educational
13 program to tell people that that really has some
14 significance. What they put on now, as you know, is a
15 little label on the back side of a prescription label
16 on a bottle that says caution or warning, this drug may
17 be sedating, may cause -- do not operate machinery,
18 drive a car, etc. It is a warning.

19 It's a well-known fact that a lot of people
20 who get prescriptions in this country really don't
21 understand the prescription label itself, let alone
22 some of the warnings that are attached to it, and
23 sometimes there are more than one warning attached to a
24 prescription. There may be two or three.

1 When they turn that over and start reading
2 them, multiple warnings tend to have a lessening impact
3 on the observer. They see all this, and they start
4 wondering what it really means.

5 The one about sedation, and we've all taken
6 sedating antihistamines by prescription or over-the-
7 counter, and you were aware of these warnings, and you
8 read them, and they tend to really not excite you too
9 much because I've taken them, and I've not felt that
10 I've experienced the effects.

11 I guess what I'm saying is to put the red
12 triangle on or something similar to that, we're having
13 a hard time understanding how that might improve the
14 label now that is in English. You can read it, and you
15 have, I think, a better understanding of it, unless
16 again you can educate the consumers that this now has a
17 new meaning, like the radiation symbol in this country.

18 Everybody understands what that means, and if they see
19 it on any product, it catches their attention because
20 they've been educated to it.

21 When I read this again in the docket, I had
22 some problem with the triangle concept, something
23 without words, because I'm not sure again that you're
24 going to be able to do this in the minds of the

1 consumer, that they see this little red triangle or
2 yellow circle or whatever you make it on a
3 prescription, that it's going to have the same impact
4 as a label where, if they read it and understand
5 English at a certain level, they will at least
6 comprehend what that little thing means.

7 So, I guess I would throw it back and say
8 unless you're willing to undertake a really massive
9 education program when you undertake something like
10 this, I think you probably will have great difficulty
11 with it at first.

12 So, it's possible that it could work, but it
13 would have to be proven that it's any more effective in
14 a way than what's put on there now. Unless you mandate
15 that a certain level developed by FDA, which we'd
16 probably agree with, the agency, along with its
17 consultants and the public, looking at a prototype
18 product would agree that that's better than what's put
19 on there now by pharmacists, we would be happy to do
20 that, if that can be improved, if you can get the
21 attention of the public who reads those labels, but
22 that system in use in Sweden and Australia may work
23 there, although I haven't seen any data here that it
24 really works. It just says it's being implemented.

1 So, we're agreeable to something that
2 improves the present system, but it's a hypothetical to
3 know whether that can be made to work in a short period
4 of time or even in a longer period of time.

5 DR. GARBER: So, do I understand correctly
6 that the position would be that if a warning label were
7 developed that could be shown to be more effective than
8 current warning labels, that your organization would
9 find that to be an advantage over the current system
10 and would voluntarily use such a system?

11 DR. MAY: I would say that's true, using the
12 caveat that I used, that it is a better system and
13 would have a better impact on the consumer or even on
14 anyone taking a product. That's right.

15 DR. GARBER: Okay. You mentioned that the
16 requirement of affixed labels is really a best
17 practices requirement; that is to say, that it's done
18 because it is a standard of practice in the pharmacist
19 community.

20 So, do I understand correctly then that there
21 is no state law, federal law, regulatory guidance that
22 would suggest that you must put any warning label on a
23 prescription medication?

24 DR. MAY: Oh, no. There are some warning

1 labels that are required to be put on the medication,
2 but what you would hope for, what we would hope for
3 would be if you could come up with a very effective
4 warning, which would help solve this problem, if that
5 could be made a federal standard, it would make it a
6 whole lot easier for the 50 states to adopt as opposed
7 to state regulations which may vary all over the place.

8 One state may make it a regulation, another one may
9 make it simply a good practice.

10 Pharmacists put a lot of these labels on
11 because it is good practice. Whether or not there are
12 state laws, I cannot tell you in all states. I'm here
13 to talk about the overall general concept of trying to
14 improve the labeling put on there now.

15 It was mentioned in here by NTSB that
16 something that was -- I think I read it, something that
17 was in a mandate would work a lot better, but again you
18 have to prove that there should be a federal or state
19 requirement for it as opposed to standard practices.

20 DR. GARBER: And actually, my next question
21 goes to Mr. George in regard to that same issue.

22 How many states actually have laws that
23 specifically prohibit use of impairing medications? Do
24 you have any feel for whether most or many states have

1 such laws?

2 MR. GEORGE: I can tell you what we have in
3 Delaware. My thought is that probably every state has
4 a similar DUI statute that prohibits not only the
5 driving while under the influence of alcohol but of an
6 impairing drug as well. So, I would have to say that
7 my feeling is that probably every state has some
8 statute.

9 DR. GARBER: You mentioned some of the
10 difficulties inherent in trying to prosecute a case
11 involving medication versus one involving alcohol or, I
12 assume, illicit substances as well.

13 Does -- do you believe that there are -- that
14 there is less activity on the part of law enforcement
15 in trying to determine whether people may be impaired
16 by drugs or perhaps even if that determination is made,
17 given the very difficult hurdles that may need to be
18 cleared to prosecute such a case, that such cases are
19 not -- even when found, may not necessarily be
20 prosecuted or evaluated completely?

21 MR. GEORGE: Well, I think the problem with
22 an impaired driver, impaired by medication, is that the
23 impairment has to be such that they're falling down
24 drunk, like an alcohol-type case.

1 Police are limited in what they can do, based
2 obviously on the Constitution. Before they can take
3 blood samples or urine samples or an intoxilyzer, there
4 has to be probable cause. So, the person that they
5 stop has to exhibit some type of outward signs of
6 intoxication. That's the first hurdle.

7 If they are impaired to the point where they
8 can't do field tests, the standardized field tests,
9 then the next step would be the officer is probably
10 going to assume that they're impaired by alcohol. He's
11 going to probably take them back to the troop and give
12 them an intoxilyzer.

13 The problem there is he's going to get a 00
14 reading, and he doesn't know what to do then. It looks
15 like the person's drunk. They're showing no reading,
16 and they're sort of stymied at that point, and that's
17 the problem with the training at this level in the
18 state of Delaware.

19 DR. GARBER: So, if we were to look at a
20 database, a hypothetical database of non-fatally-
21 injured drivers or drivers who were potentially at
22 fault in a traffic accident, would it be safe to say
23 that we would probably under-represent the risks
24 associated with the medications simply because it's so

1 difficult to detect, and if one detected, difficult to
2 -- or suspected, difficult to prove?

3 MR. GEORGE: Absolutely. I would agree with
4 that.

5 DR. GARBER: Okay. I may have a couple more
6 questions, but that's all I've got for now.

7 DR. ANDREASON: This is a question for Mr.
8 George, but Dr. May, if you happen to know the answer
9 to this, too.

10 What are the -- do you have a list of drugs
11 that are considered impairing or is that statute fairly
12 open to interpretation?

13 MR. GEORGE: When it comes to -- the statute
14 reads it prohibits the driving of a vehicle while under
15 the influence of any drug or under the influence of a
16 combination of alcohol and any drug, and we obviously
17 take that to mean both legal and illegal. So, that's
18 exactly how our statute reads. So, it would encompass
19 legally-prescribed drugs, if it impairs you.

20 DR. ANDREASON: Any drug?

21 MR. GEORGE: Any drug.

22 DR. TEMPLE: Is under the influence described
23 further?

24 MR. GEORGE: It is defined, but I can't

1 specifically say how it's defined right now.

2 DR. TEMPLE: Is there something that implies,
3 though, that your performance is impaired?

4 MR. GEORGE: Yes.

5 DR. TEMPLE: Okay. But it doesn't give any
6 hint as to what kinds of drugs might be there? You're
7 on your own?

8 MR. GEORGE: You're on your own.

9 DR. ANDREASON: So, if someone had a blood
10 alcohol level that was, say, below .02, and they were
11 taking a non-steroidal anti-inflammatory drug, that
12 would be considered in combination with alcohol?

13 MR. GEORGE: Well, our statute has -- sets
14 out five different definitions of being impaired. It
15 speaks specifically to alcohol, and in our state, a
16 reading of .01 or above is considered under the
17 influence. A reading from .05 to .09 is presumptive
18 evidence that you're under the influence, and a reading
19 of .05 and under is not considered under the influence.

20 So, in your example, a reading of .02 and an
21 indication that there was some other drug involved,
22 that case, if we were to take it to trial, we would
23 have to have evidence of beginning first with the field
24 tests that are performed by the officer, and I'm

1 assuming everybody knows what I mean when I talk about
2 standardized field tests. They're the walk and turn
3 test, the picking up the keys, the counting, the
4 alphabet, reciting the alphabet. In some instances,
5 tests involving HGN, and those -- the performance on
6 those tests would have to be so poor because that would
7 in essence be all the evidence to make or break this
8 particular DUI case because obviously when you take
9 that individual back to do an intoxilyzer reading, it's
10 going to come back with an .02.

11 So, to prove that case, you're going to have
12 to have pretty poor performance on the field tests to
13 be able to obtain a conviction. Now, whether steroid
14 drugs would cause a person to perform that poorly, I
15 can't speak to that.

16 DR. ANDREASON: What kind of field -- now,
17 you described a field test. How do those correlate to,
18 say, driving performance? I assume they've already
19 been pulled over because of some erratic driving. Why
20 do the field tests need to be repeated?

21 MR. GEORGE: Because an officer can't take
22 someone into custody without probable cause. That's
23 one of the fundamentals of our Constitution. The
24 officer begins his case by noticing the erratic

1 driving. That gives him the reasonable suspicion to
2 stop the driver and then begin the process of
3 developing probable cause, what we call probable cause.

4 The erratic driving is the first thing.

5 The next thing that a trained officer will do
6 is he'll go up to the car, and he will look into it,
7 you know, see if he gets the odor of alcohol. There's
8 initial signs of impairment, such as speech, looking at
9 their eyes to see if they're bloodshot, and some of
10 these signs will be the same if someone's impaired by
11 medication versus alcohol.

12 Obviously if they're impaired by medication,
13 you're not going to get the smell of alcohol. He's
14 going to ask for their driver's license, registration,
15 and he's going to look to see if they have difficulty
16 in the pulling out of the glove compartment or out of
17 their wallet, if they fumble with them, if they give
18 them their Acme card instead of their driver's license.

19 Those are the first things that he's noticing.

20 At that point, as he continues to develop his
21 probable cause, he's going to ask the driver to get out
22 of the car. Again, he's going to note whether they had
23 difficulty in getting out of the car, whether they had
24 to lean on the car, whether they stumble, and again,

1 he's developing probable cause. He doesn't have it
2 yet.

3 He'll then give a series of field tests and
4 note the performance. Now, I'm not an expert in field
5 tests, but I know that NHTSA has done a number of
6 studies, and I can't tell you the percentages off the
7 top of my head, but I know that the studies have shown
8 that if you fail certain -- and NHTSA, I think,
9 recommends three standardized field tests, and if you
10 fail these field tests, there's a 70-percent likelihood
11 that you are probably under the influence of alcohol.

12 Combine that with an HGN test, which not all
13 officers are trained to do, your percentage goes even
14 higher, that the person is most likely under the
15 influence. At that point, the officer has developed
16 his probable cause that he needs to either give an
17 intoxilyzer or to take blood. So, it's a step-by-step
18 process to that point of actually being able to give
19 the field tests. You just can't stop someone, anyone
20 you want and say, hey, I'd like you to do some field
21 tests for me. It's a step-by-step process.

22 DR. TEMPLE: Once that test establishes
23 probable cause, then they can make somebody exhale into
24 an analytic procedure?

1 MR. GEORGE: At that point, he has
2 established probable cause. He can arrest the
3 individual and either take them back to the troop and
4 give them the intoxilyzer or, in his discretion in our
5 state, take the blood test.

6 DR. TEMPLE: Okay. I was going to ask about
7 saliva tests, but he can get a blood test in Delaware?

8 MR. GEORGE: Well, our statute specifically
9 requires a blood test. At one time, it provided for a
10 urine test, but that was never done, and it was really
11 meaningless.

12 DR. ANDREASON: Field testing does seem to be
13 weighted to detect alcohol, especially with horizontal
14 gaze and walking a straight line, which are cerebellar
15 functions.

16 If someone was impaired, say, by other drugs
17 that didn't affect cerebellar functions, what would the
18 officer be able to do? Must they fail these tests in
19 order to be tested or to obtain a blood test?

20 MR. GEORGE: Keep in mind, I'm not a chemist,
21 I'm a practicing prosecutor.

22 DR. ANDREASON: Right.

23 MR. GEORGE: However, I'm not sure I totally
24 agree with you. I do know about the DRE program.

1 We've -- I've -- we initially had a conference in
2 Delaware at one point where we brought out Sgt. Tom
3 Paige, who helped to develop it in L.A., and I know
4 that with a drug recognition expert, who is a trained
5 police officer, who is ultimately based on his training
6 able to detect or determine seven broad categories of
7 possible drug impairment, they begin with the
8 standardized field tests.

9 So, the standardized field tests not only are
10 geared towards alcohol but are geared for drugs as
11 well. The HGN test is geared not only for alcohol but
12 for drug impairment as well. The problem is, that's
13 the extent of the training for most police officers.
14 The training necessary to later determine whether it's
15 a drug impairment is much more extensive, and in
16 Delaware, we don't have such a program. That's where
17 the problem comes with detection of drug impairment.

18 DR. TEMPLE: Do you have programs for
19 obtaining blood samples from people killed in accidents
20 and other people in the car? Still thinking
21 epidemiologically from the last panel, but I just
22 wondered if that was a resource.

23 MR. GEORGE: Well, anyone who's killed in a
24 motor vehicle accident is taken to the state medical

1 examiner's office. Keep in mind, Delaware being so
2 small, everything's sort of run at the state level. We
3 have no county district attorneys, no county MEs, and
4 so, everyone in Delaware who would be killed in an
5 accident would be taken to the ME and an autopsy
6 performed and blood tests. So, yes, absolutely.

7 DR. TEMPLE: Do you know, have data ever been
8 looked at to compare blood levels of various substances
9 of interest in drivers and passengers or anything like
10 that been published?

11 MR. GEORGE: I know that our Safety Council
12 does publish yearly the statistics involving
13 fatalities, and I know that they keep track if the
14 driver of the automobile has -- was intoxicated. I do
15 know that. Whether they look for other drug
16 impairment, I don't know.

17 MR. KOTOWSKI: In the case where an
18 enforcement -- where a motorist is stopped and is
19 pulled over at the roadside and has been subjected to
20 these battery of tests and obviously there's some
21 difficulty, when it comes time when we have a blood
22 test that is drawn, do we have to be specific about a
23 particular type of drug or is there just a general
24 screen or a general scan that would be taken of that

1 particular drug sample?

2 MR. GEORGE: Again that's a little bit out of
3 my area of expertise, but based on some experience I've
4 had in that, I know they always check for alcohol. I
5 know that they always check for certain illegal
6 substances, PCPs, cocaine, and several others.

7 I don't believe, unless they are specifically
8 advised, that they would look for an illegally-
9 medicated type of drug, unless it's some type of
10 barbiturate, illegal barbiturate.

11 MR. KOTOWSKI: If you could, could you walk
12 us through your procedure as a prosecutor, some of the
13 difficulties you would face, that if you had a motorist
14 that was stopped, that failed all these tests, had a
15 blood sample that was taken, came back positive for
16 some type of a prescription drug, that when you checked
17 the PDR, it says that it is a sedative-type medication?

18 You have a reading that there was a certain
19 percentage or a certain level of this particular drug
20 in that person's blood system, the big AC level is
21 about .07, what would you have to do in order to
22 provide for a successful prosecution about the
23 establishment of the effects of that particular drug?

24 MR. GEORGE: That case may be a little easier

1 to speak to because we have an .07 alcohol and that's
2 within the range where the trier of fact, whether it be
3 a judge or a jury, could find a person under the
4 influence of alcohol or a combination of alcohol and
5 drugs.

6 Again, any time that you have a finding where
7 there's some type of drug involved, and a finding where
8 the blood alcohol is under 10, the prosecutor has to
9 really rely on the performance on the field tests to
10 prove that the person was impaired.

11 Without a very poor showing on the field
12 test, you're going to have difficulty in obtaining a
13 conviction. It is possible, and I've done this in
14 several cases, depending on the blood reading of the
15 drug that's detected, that we would bring in one of our
16 forensic pathologists, one of our assistant medical
17 examiners, to speak to that particular drug.

18 I certainly know in instances where we find
19 illegal substances, like cocaine or PCP, the medical
20 examiners are usually quite willing to come in and talk
21 about the effects of that particular drug and whether
22 it would impair you or not, but again the issue for the
23 trier of fact is, was this person impaired?

24 They're going to be looking. They're going

1 to focus mainly on the field tests, and unless we have
2 some kind of expert testimony regarding the effects of
3 that, that finding of the drug may or may not be that
4 important to us.

5 MR. KOTOWSKI: So, in most cases then, for
6 any particular type of drug, then it would almost
7 necessitate the testimony of an expert witness?

8 MR. GEORGE: It would always require the
9 testimony -- well, no, I don't want to say that.
10 Again, if the field tests are just so poor, and again
11 I'm going to kind of refer back to an alcohol-type case
12 where the person looks like -- who is literally falling
13 down drunk, then I'm not going to need an expert.

14 But if the field tests were so-so, then
15 without an expert, there's no case.

16 MR. KOTOWSKI: And the reference that you
17 made to the DREs, the drug recognition experts, do you
18 know how long that training program lasts to train an
19 officer as a DRE officer?

20 MR. GEORGE: I don't, but I know that after
21 the training, I think that they require at least 90
22 hours of field experience with other DREs and working
23 at hospitals before they actually go out and start
24 working on the streets.

1 Part of the training for a DRE involves
2 taking vital signs, measuring the pupil, and I think
3 that that training, the 90 hours, is done in hospital
4 emergency rooms.

5 MR. KOTOWSKI: And do you have any idea of
6 how long it would take for a drug recognition expert to
7 make a stop, identify a person that's been under the
8 influence of some type of drug and be tested and
9 arrested as compared to a person that's under the
10 influence of alcohol?

11 MR. GEORGE: Well, it's usually the DRE isn't
12 making the stop. The stop is made by another police
13 officer, and the DRE is called in afterwards to
14 basically do the field tests and conduct this
15 examination. As to how long it takes, I don't know.

16 DR. ANDREASON: Dr. May, I had a question
17 about how do you determine which drugs you put a label
18 on or a warning label on for supervision.

19 For example, is it from product labeling or
20 is there some other source of information that you use
21 to place the label on?

22 DR. MAY: It would be my understanding that
23 the pharmacist, from his knowledge of the drug being
24 dispensed, there is -- when he opens up the bottle of

1 pills, if there's nothing on the federal label that
2 says you must put a sticker on this, but if he's
3 dealing with antihistamines, dealing with drugs that he
4 knows to be sedating, whether it's the benzodiazepines
5 or antihistamines or whatever, from personal knowledge,
6 experience and training, he knows that label goes on
7 there to warn the person that this may cause problems
8 if they operate an automobile or heavy machinery.

9 I'm not aware that there's any -- I haven't
10 worked in a pharmacy for many years, but there was
11 never a federal requirement that that label had to go
12 on there. When the state board people inspect and go
13 back and look at the prescriptions to see if they're
14 adhering to this, they'll look for any prescription
15 that they know to be sedating, and these don't carry
16 any particular mark on the computer file or in a hard
17 copy file as narcotics would.

18 They're looking for the names of drugs and
19 knowing what they cause, and they're looking to see if
20 in fact a label was put on there by the pharmacist.
21 They'll watch pharmacists fill prescriptions, but
22 that's how the system operates. It's a professional
23 knowledge. There is no chart they look at that says
24 you have to put this on for this class of drugs -- for

1 class of drugs but not specific drugs.

2 DR. ANDREASON: Another question is, do you
3 have any idea how much sedation is necessary before a
4 label goes on? For example, I've received
5 prescriptions for Naprosyn that have a warning label
6 that it could be sedating.

7 DR. MAY: To my knowledge, that information
8 does not exist. Pharmacists do not use that. You're
9 getting Benadryl or you're getting another
10 antihistamine, you're taking one three times a day or
11 you're taking two every four hours, when the dose is
12 much higher in one case over a 24-hour period, the same
13 label goes on the product, warning, based on the drug
14 itself, because a lot of people will get a
15 prescription, especially over-the-counter drugs, and
16 will overdose. They will take more than the
17 indication.

18 It says one three times a day, and it's an
19 antibiotic, they may take two. They may take more than
20 the indicated. So, you put the label on based on the
21 pharmacology of the drug. If it has the property,
22 propensity to be a sedating drug, you put the warning
23 on it, regardless of the blood levels the patient may
24 experience from taking it for different levels of the

1 drug.

2 DR. ANDREASON: Thank you.

3 DR. ELLINGSTAD: Anything else from our Tech
4 Panel?

5 (No response)

6 DR. ELLINGSTAD: Okay. We'll go to the
7 parties, and let's start with the Advocacy Group this
8 time.

9 MS. TARNEY: This is for Jon May. Are you of
10 an opinion that pharmaceutical care these days means
11 that the pharmacist can be held accountable for
12 reaching or for resolving patient needs related to the
13 medication taken as directed?

14 If so, would you think it's possible in the
15 present situation or the near future that a pharmacist
16 advises the prescriber and the patient to use the least
17 impairing drug in case the first time prescription for
18 a hypnotic, let's say, shows a severely impairing drug?

19 In other words, can the -- do you see in the
20 future where the pharmacist could take the role of an
21 advisor to the physician as well as to the patient?

22 DR. MAY: I'm glad you raised that. Yes, I
23 firmly believe in that. NABP believes in that, and all
24 of the pharmacy professional associations I know

1 believe in that. The paradigm has shifted where
2 pharmacy is no longer just filling prescriptions,
3 counting them, licking them, stamping them, pouring.
4 That's being done by technicians hopefully, and the
5 pharmacist is counseling the patient. The pharmacist
6 is specifically making sure the patient understands the
7 drug they're getting, what did the doctor tell them
8 about it. If that's inadequate, reinforcing what they
9 need to know.

10 The Keystone Group met several years ago and
11 developed a mandated written information system for
12 people receiving prescriptions under a federal statute.

13 It was a rider to a federal bill, and one of the
14 things missing in that, in my opinion, is, although
15 they give very good printed information today when you
16 get a new prescription, you get an insert that tells
17 you all about that drug. There's a tremendous amount
18 of information in there in the case of sedating
19 antihistamines, in the case of benzodiazepines, etc.
20 It warns about this particular drug.

21 But unfortunately, what a lot of pharmacists
22 are doing is putting that little information pamphlet
23 on the bag with the prescription, and they slide a
24 piece of paper in front of you, and when you look at

1 it, it says do you wish to be counseled? That's
2 inadequate in my opinion. That's inadequate in NABP's
3 opinion, because too many people say, oh, no, I'm in a
4 hurry, I don't need it. They X it out, and they go,
5 and unless they open up that pamphlet and read the
6 information, they really don't know much more about the
7 drug than what was provided to them.

8 The role of the pharmacist, in my opinion,
9 and it will happen over a period of years, is he will
10 take every patient, and he will go over that drug with
11 them, and he will not only show them the pamphlet, but
12 he will reinforce parts of it.

13 One of the beauties if you go into a system
14 where you're worried about these drugs that can cause
15 these problems with pilots and with operators of heavy
16 machinery as well as the consumer is they have to be
17 made aware of the very thing you're talking about.
18 These drugs have potential dangers to them, and you can
19 reinforce that best when that person gets that
20 prescription at the pharmacy, and the pharmacist tells
21 them that. Oh, by the way, do you see this little
22 label on here? See this little red triangle or
23 whatever? This means that this product has the
24 potential for.

1 You focus it in their minds, so when they
2 leave, then they read the information pamphlet, that's
3 going to stay with them. They're going to react to
4 that. They're going to be aware of that. They may
5 continue to ignore it, but you've made your point of
6 reinforcing it in their minds.

7 Today, that does not exist adequately enough,
8 but it is changing because the role of the pharmacist
9 is changing, working more closely with physicians in
10 delivering health care, not just delivering a
11 prescription, and making sure that the ultimate end
12 result occurs when they take that prescription.
13 They're taking it right. They're taking it in the
14 right amount of time, and they know what they're
15 taking.

16 So, that's what pharmacy is coming to, and
17 that can fit in well with this type of approach where
18 you're changing -- hoping to change a labeling system
19 and an awareness on the part of the public that these
20 drugs are not just innocuous things you're taking, and
21 they get that reinforced in their minds in some
22 respects by getting no information from either the
23 doctor or the pharmacist in some cases. They just get
24 this prescription that says take one three times a day,

1 and they start taking it.

2 No awareness of what this is supposed to do
3 or the side effects that can result from it, unless
4 they get counseling, unless they read this information
5 they get. So, that's a long way of saying yes, I agree
6 with you, and that's what pharmacy is changing to, and
7 if that was done today in this instance, you would not
8 see some of these accidents, I'm sure, because the
9 patients would have been told right up front beware,
10 this drug can really produce sedating effects and don't
11 do some of these things, along with an education
12 program for people like pilots, etc., that's the other
13 aspect of this.

14 It kind of intrigued me when I read it. You
15 can do all the labeling you want in the world, but
16 unless you educate the segment of the population that
17 has responsibility for flying \$20 million airplanes
18 with 300 people in them that they shouldn't take
19 certain drugs or if they are, they should advise their
20 surgeons that operate over them that they're doing this
21 and get permission to do it, get some awareness of it,
22 we're going to continue to have problems, and you do
23 focus on education in here, but that's a big aspect of
24 it, also.

1 I'm talking about the pharmacists educating
2 people when they pick up prescriptions as well as
3 labeling. Labeling can only go a certain way. The
4 rest of it is education and making people aware of what
5 they're supposed to do and the danger of these drugs
6 they're taking and some of the side effects.

7 MS. TARNEY: Do you see the role of the
8 pharmacist also to question a physician if the
9 pharmacist is seeing something that is not safe?

10 DR. MAY: Absolutely. When I graduated from
11 pharmacy school in 1959, I was -- we were all afraid to
12 call a doctor. We were afraid of what he'd say. What
13 the hell are you calling me for? Just fill the
14 prescription, and I ran into people when I was with the
15 government and at NIH. NIH physicians basically told
16 me that. You fill the prescription, I wrote it, don't
17 question me.

18 Today, that's totally changed. Pharmacists
19 are calling physicians and saying, in hopefully a
20 tactful way, doctor, I've talked to the patient, and
21 this drug, I think this drug is either contraindicated
22 or are you aware that the patient is already taking
23 another drug which they probably weren't aware of.
24 They're interacting with the physicians because the

1 bottom line is the outcome of the case, the patient
2 getting better taking the drug.

3 The only way to do that is if pharmacists
4 start becoming more interactive, working with nurses
5 and physicians, to make sure that the system really
6 benefits the patient, not the physician, not the
7 pharmacist. They're secondary to the patient and
8 that's another whole shift in this thing coming.

9 I can go on for hours about these protocols
10 being developed between physicians and pharmacists
11 today, where the pharmacist actually delivers care.
12 They do -- they take blood. They determine Dilantin
13 levels. They determine levels of drugs, working with
14 physicians under protocol, because the physician then
15 can spend more of his time doing the diagnosis, doing
16 the prescribing but not having to do some of that other
17 information. They're counseling patients who have
18 asthma, so that they don't go back to the doctor and
19 say Doc, this medicine isn't working, when you find out
20 they're not using the inhaler right. They learn to do
21 that from the pharmacist.

22 A system that works hand-in-hand is going to
23 result in better care in this country. So, that's
24 changing rapidly today, I'm happy to say. It's moving

1 forward in every state in the Union.

2 DR. ELLINGSTAD: Okay. Let's go to the
3 Government. Mr. Clarke?

4 MR. CLARKE: Mr. George, you indicated that
5 the procedure seems to be field tests and then an
6 intoxilyzer and then blood possibly or can you go from
7 positive results in a field test straight to blood and
8 skip over the intoxilyzer?

9 MR. GEORGE: That's at the discretion of the
10 police officer. Another one of the possible tests is
11 what we call a PBT, a portable breath test. That gives
12 an initial unscientific, I guess, reading of the blood,
13 and if that were to come back 00, if the person has
14 been done so poorly on the field test, then the
15 officer, in his discretion, can have a blood sample
16 taken.

17 In fatal cases, we usually take blood because
18 we're -- we don't do an intoxilyzer. We take -- once
19 we've developed a probable cause, we'll have blood
20 taken because we're always suspicious of whether
21 there's alcohol, drugs or a combination of both
22 involved.

23 MR. CLARKE: You mentioned that there was
24 some number of drugs that you test for, in addition to

1 alcohol, and I presume those were all illegal drugs.

2 If you get a situation in which you've gotten
3 poor field test results but zero readings, say, on an
4 intoxilyzer and this other test, and you get some kind
5 of positive readings on any of these illegal drugs,
6 what success do you have then in prosecuting those
7 cases?

8 MR. GEORGE: Well, again, it's really going
9 to depend on the field tests because I'm not sure it
10 makes much difference. Obviously with an illegal drug,
11 it's more prejudicial when you present it to a jury,
12 but ultimately again, the issue is one of impairment,
13 being under the influence.

14 When we get the blood test back, if it's a
15 legal drug or an illegal drug, I'm still going to have
16 to prove that the person was impaired by that
17 particular drug. I suppose you can take small amounts
18 of cocaine and still drive a car and not be impaired,
19 just like there are a number of legal drugs that you
20 can take and not be impaired.

21 The problem that we have is when we get that
22 blood test back, and I take it to one of my experts,
23 and I say, look, at this reading and tell me what it
24 means, and if it's a legal drug, he's probably going to

1 tell me, well, that's a therapeutic dose. That's very
2 nice. What does that mean? There was a therapeutic
3 dose in this person's blood. Does that mean he was
4 driving under the influence? I don't know.

5 MR. CLARKE: So, if you get low levels of any
6 of these drugs, but you've still got poor field test
7 results, you don't have the basis for going forward
8 with the prosecution?

9 MR. GEORGE: Without the poor field tests, we
10 won't have the basis. Again, you know, the therapeutic
11 dose, the fact that it's in the blood may be relevant,
12 may not be, but we're really going to have to rely on
13 the field tests to be able to prove that.

14 MR. CLARKE: Is that the most convincing
15 aspect of a prosecution or are these quantitative
16 measures more compelling?

17 MR. GEORGE: No. The field tests are
18 absolutely the most compelling part. Really, as far as
19 drugs are concerned, and unless the dose is just so
20 high, the quantitative effects really can have a lot of
21 meaning to the prosecution.

22 MR. CLARKE: Are there any cost
23 considerations associated with making decisions to draw
24 blood as opposed to just relying on the intoxilyzer

1 results? If you were routinely doing this on large
2 numbers, how would -- what would that do to your
3 budget?

4 MR. GEORGE: Well, again, the decision is at
5 the discretion of the police officer, and then I think
6 -- and I'm not a police officer, but I would think that
7 some of the factors that go in his decision whether to
8 take blood or intoxilyzer is that the intoxilyzer is
9 easier. He has to go back to the troop and do it,
10 takes about 30 minutes all together. He's at the
11 troop. He can write his reports versus having to take
12 a blood test requires him going to the emergency room -
13 -

14 MR. CLARKE: Right. But we're talking about
15 situations here where presumably the intoxilyzer tests
16 are negative. In other words, just -- we're looking at
17 just effects of prescription or OTCs, without
18 confounding effects of alcohol.

19 MR. GEORGE: Well, if he's already given an
20 intoxilyzer, then he's not going to take blood, too.
21 He makes that decision at the time.

22 MR. CLARKE: So, to get a zero reading on the
23 intoxilyzer, you can take blood?

24 MR. GEORGE: Probably not.

1 MR. CLARKE: Even though he had poor field
2 tests?

3 MR. GEORGE: He's going to probably assume it
4 was alcohol. He made the decision before he leaves the
5 scene and of whether he's going to take the blood or
6 intoxilyzer, and once he makes the decision, he's not
7 going to do both.

8 MR. CLARKE: But I guess my question is, if
9 he does poorly on the field tests, giving the officer
10 an indication of probable cause, then goes back to the
11 police station, I presume that's where they go, and
12 then gives them an intoxilyzer test and gets zero, then
13 what happens?

14 MR. GEORGE: He's unlikely to then -- on just
15 a regular DUI, it's very unlikely that he's then going
16 to take him to a hospital and do blood work.

17 MR. CLARKE: So, I guess what I'm trying --
18 what has to be present for the person, for the officer
19 to decide to draw blood? A pretty bad field test and
20 the intoxilyzer or just one or the other?

21 MR. GEORGE: Well, maybe I haven't made
22 myself clear. The officer has some -- can do either.
23 He can either give an intoxilyzer or he can decide to
24 have blood taken. In fatal cases, we make the decision

1 right at the scene that we're going to have blood
2 taken. We're not even going to bother with the
3 intoxilyzer.

4 Once the officer takes that person into
5 custody, arrests them, he makes the decision, am I
6 going to take him to the emergency room and take blood
7 or am I going to take him down to the troop and give
8 him the intoxilyzer? He makes that decision at the
9 scene. He doesn't know what the reading's going to be,
10 but he's making the decision of these two options. I'm
11 going to do one of them.

12 Once he makes that option, he takes them back
13 to the troop. He gives them the intoxilyzer. He comes
14 back 00. In a DUI case, it is very unlikely that he
15 then is going to turn around and take the person back
16 to the emergency room and take blood.

17 MR. CLARKE: I guess also, I'm looking at it
18 from your point of view as a prosecutor. You've got
19 this information in hand, say poor field test results,
20 zero -- he just went right to a blood test because
21 that's it, and you've got zero blood alcohol but maybe
22 trace levels of some of these five illegal drugs, one
23 or more of them say, let's say one that you're talking
24 about. What do you do as a prosecutor at this point?

1 MR. GEORGE: I'm going to talk to my experts
2 and try to determine if the therapeutic level -- what
3 the therapeutic level of that particular drug, what it
4 means. Will they testify that that level is impairing?

5 But even with their testimony that that is an
6 impairing level, I'm going to still need poor field
7 tests to be able to convict that person of driving
8 under the influence. The level itself, unless it's
9 just incredibly high, is not going to be sufficient to
10 sustain my burden, which is to prove someone guilty
11 beyond a reasonable doubt.

12 MR. CLARKE: Thank you.

13 DR. ELLINGSTAD: Let's go to the Professional
14 Group.

15 MR. GELULA: Thank you. I have two
16 questions, the first for Mr. George.

17 Today, we've mostly been focused on sedating
18 medications, drug interactions and combination of
19 sedating medications with alcohol, but a number of
20 studies have also shown that total hours of wakefulness
21 or sleep deprivation can cause impairment as great or
22 equal to alcohol intoxication.

23 I'm wondering if, in your experience, there's
24 been any evaluation or roadside tests whether there's

1 any effort to judge whether there's an additive effect
2 of sleep deprivation or time of day, the circadian
3 effect, and such. Would those factors come in?

4 For instance, if it's been adjudged that the
5 person has been up for the past 24 hours, is that a
6 factor that you use in trial?

7 MR. GEORGE: Absolutely, and I have done a
8 number of commercial vehicle cases. In particular, I
9 finished one up about a year and a half ago that you
10 may be familiar with. A truck driver coming down a
11 major roadway in Delaware came up on a red light.

12 All the cars were stopped, and he plowed into
13 this row of cars. The van that he initially struck was
14 totally demolished, burst into flames, people burned to
15 death, and we ultimately were able to show that over a
16 -- he had a GPS system in his truck, and we were able
17 to show that over approximately 55-57 hours, that he
18 had been on the road for close to -- all but for about
19 13 hours, just way over his hours, and that obviously
20 was a factor in whether we were going to charge him.

21 Keep in mind that not every fatal motor
22 vehicle accident involves a criminal prosecution. In
23 Delaware, we need to rise to the level of what we call
24 "criminal negligence", which is a much higher standard

1 than just simple negligence.

2 People who negligently kill other people are
3 not prosecuted criminally. They may be sued, but they
4 are not prosecuted criminally. So, we had to make a
5 case of criminal negligence. Obviously part of that
6 case was the fact that he didn't see all these cars
7 stopped at a red light. He plowed into them at 60
8 miles an hour, but the other major factor in that
9 particular case was the number of hours that he had
10 been up, and I think that played a very important
11 factor in our successfully convicting that driver.

12 MR. GELULA: Thank you.

13 And Dr. May, I'm curious if in your
14 experience or if there's evidence to suggest that
15 patients might be substituting an over-the-counter
16 drug, if they make that choice, instead of going for
17 the filling of a prescription or, for instance, a
18 hypnotic because they might believe that the OTC brand
19 is safer. Do patients make that kind of decision?

20 DR. MAY: I missed the last -- your last
21 comment, the last words you used.

22 MR. GELULA: They might believe that the OTC
23 brand is safer than the prescription drug. Do they
24 make a substitution?

1 DR. MAY: I really can't comment on other
2 than drugs that exist for both prescription and over-
3 the-counter. There are people who will buy a Motrin
4 prescription, a high-dose prescription, low-dose over-
5 the-counter, people buy low-dose over the counter
6 because they don't go to a physician to get a
7 prescription. I'm sure that goes on.

8 Other -- going to other drugs, I really can't
9 comment on that.

10 MR. GELULA: Thank you.

11 DR. ELLINGSTAD: Thank you.

12 The Pharmaceutical Industry? Would you make
13 sure your button is up?

14 MR. LISTER: I'm Steve Lister. I'm with the
15 Consumer Healthcare Products Association.

16 DR. ELLINGSTAD: Could you say your name
17 slowly, so we can get it?

18 MR. LISTER: Sure. Steve Lister.

19 DR. ELLINGSTAD: Lister?

20 MR. LISTER: Lister, like mister. I'm with
21 the Consumer Healthcare Products Association, and I
22 don't think I have any questions for the panel.

23 DR. ELLINGSTAD: Thank you.

24 The Union Group?

1 CAPTAIN POPIEL: No questions.

2 DR. ELLINGSTAD: Thank you.

3 And finally, the Transportation Industry
4 Group?

5 DR. FAULKNER: Yes, I have a question for Dr.
6 May. Habla Espanole? Sprechen sie Deutsche?

7 The reason I ask is, you know, we're in an
8 international business with airlines, trucking, things
9 like that. I certainly admire and support pharmacists
10 working and explaining things, but we're going to hit
11 language barriers, and one thing I've encountered or
12 it's been encountered here is warning labels will often
13 have pictures, but those vary from someone sleeping in
14 a bed to drowsy eyes to the like.

15 Has there been any move or is your
16 organization advocating for perhaps more picture-type
17 warnings for perhaps the illiterate or people from out
18 of country for warnings?

19 DR. MAY: Yes. NABP is certainly in favor of
20 these pictograms that we put on prescriptions or on
21 over-the-counter drugs particularly to let people know.
22 Giant Pharmacies in this area have been very active in
23 that for years, putting -- getting the suppliers of
24 their products to put certain pictograms on there.

1 We're fully aware of the Spanish problem or
2 the language problems, rather, and communities where
3 there are major populations of Hispanic people, etc.,
4 or in California, where there are Asiatics or Asians,
5 there are pharmacies that label prescriptions in that
6 language and put warnings on in Spanish.

7 If someone speaks Spanish predominantly,
8 you're not going to hand them a product that's labeled
9 necessarily in English. So, there's a lot of that
10 going on to help the patient again get the medication,
11 so they can get the ultimate outcome from it. But a
12 lot more needs to be done.

13 DR. ELLINGSTAD: Okay. Thank you.

14 And we have some questions from the audience
15 from Dr. Galson.

16 DR. GALSON: Yes. We've got one statement
17 and really two questions. I think I'll do the
18 questions first, and if we have time for the statement,
19 I can read that. This is for Dr. Jon May.

20 Would mandating the pharmacist to educate the
21 patient in regards to certain medications causing
22 sedation and warning labels be more effective than the
23 current practice?

24 DR. MAY: I heard it, but you'll have to say

1 that again.

2 DR. GALSON: Would mandatory requirement on
3 the pharmacist that they counsel patients be more
4 effective than the current system, which is voluntary?

5 DR. MAY: Well, for Medicare patients, the
6 system is mandatory, but what happens is when the law
7 was passed and then it was implemented, there were some
8 segments of the industry that wanted to be sure, this
9 is my perspective on it, wanted to be sure that this
10 was not a very harsh implementation of the law
11 requiring that if the patient was standing there, that
12 I had to be the pharmacist and do the counseling.

13 So, it was made so that some of the
14 counseling, a technician could actually ask the
15 patient, do you want to be counseled, and then if they
16 said yes, they would call the pharmacist out, but you
17 can get around that by the way you ask questions
18 obviously. You don't want to be counseled by the
19 pharmacist, do you? Well, if you ask it that way, why
20 would I want to be counseled by the pharmacist for?

21 When I go into my drugstore, as I say, I
22 won't name them, I get a piece of paper laid in front
23 of me. Even if they didn't know me, the very first
24 time, instead of the pharmacist coming out and saying

1 what do you know about the medication you're taking,
2 and I would have said I don't know anything about it,
3 and he would have counseled me.

4 They slap a piece of paper, and I'm a
5 pharmacist. I've gone through this. I play games with
6 them sometimes. I got tired of playing games when I
7 used to tell them I'm a pharmacist, what should I know
8 about the drug I'm taking? One of them looked me in
9 the eyeball and said, "What do you want to know about
10 the drug you're taking?" This guy ought to be selling
11 cars, not a pharmacist.

12 If you do it very proactively, you do get
13 that type of counseling, but it is, to answer the
14 question, it is a requirement today that Medicare
15 patients get this.

16 What the states have done is they said you
17 can't just counsel Medicare patients, Medicaid
18 patients. So, we're going to counsel all patients, and
19 they do indeed do that, but they do it but with varying
20 degrees of success. Some stores are very proactive and
21 the pharmacist will go out and go through the very
22 litany of things I talked about, using basically a
23 system developed by the U.S. Public Health Service,
24 Indian Health Service. It's an excellent approach.

1 What do you know about the medication you're
2 taking? They know right off the bat, they need to tell
3 them something, as opposed to a piece of paper in front
4 of you. The guy's running late anyway. His car is
5 double-parked. You've got to be kidding me. I don't
6 need counseling, marks the block. They've fulfilled
7 their obligation. They fulfilled what the state allows
8 them to get by with in the implementation of OBRA '87.

9 It became convoluted in my perspective, and I
10 think in NABP's. If the law was implemented the way I
11 talked about it, where every pharmacist and every owner
12 allowed the pharmacist to do this, every chain
13 drugstore allowed the pharmacist to do this, to be very
14 proactive and counsel patients, we would have a lot
15 less problems than we have today, but a lot of that
16 still is being resisted, although more and more -- I'll
17 say, chain stores because they are the biggest
18 pharmacies today. The mom and pop stores are gone,
19 basically.

20 They have to develop an attitude that that is
21 worth spending the money on to allow the pharmacist to
22 counsel the patients and not go through this what I
23 call "shell game" with a piece of paper. So, there is
24 a law. It is being implemented, but it could be

1 implemented much more stringently to the benefit of the
2 patient if it's allowed to happen, and I don't think it
3 will happen over the next short period of years.

4 DR. GALSON: Okay. The next question is, is
5 there a way for a pharmacist to determine whether the
6 patient is taking another drug obtained from another
7 pharmacist across town? If not, is there something
8 like this enforced?

9 DR. MAY: Yes. Well, I'd have to say yes
10 partially. In many drugstores today, including a lot
11 of the chains, they have a computerized entry system,
12 where, particularly if you're getting all your
13 prescriptions filled at, say, Giant in this area or
14 CVS, in their computer, you go to one store, you go to
15 multiple stores, all the drugs you're taking are going
16 to show up in that print-out, and when a pharmacist
17 fills a prescription, he puts it in the computer to
18 have a label generated, he's going to have that sheet
19 printed out right away that has all the information on
20 it.

21 They're not stacked up in a pharmacy in a
22 full amount. That's generated by the printer right as
23 that prescription's being filled. The label comes out
24 and that sheet comes out. The information is developed

1 by other retail pharmacists. It's developed by
2 information groups that have the data. All of that
3 comes out of the printer, a computer-generated printing
4 system.

5 So, the information is there, and it can get
6 to the patient, if the pharmacist does the proper role
7 of counseling.

8 DR. GALSON: Okay. Of course, every pharmacy
9 chain has got their own system. They're not linked
10 together.

11 DR. MAY: The fact of the matter is, in this
12 country today, 95 percent of all pharmacies -- this is
13 year-old data. I don't know what -- 95 percent of
14 pharmacies one year ago had computer systems in the
15 pharmacy. Even small pharmacies realized they had to
16 have this system. They just buy the software. They
17 buy the system. It costs \$2 or \$3,000, but they have
18 to have it basically if they are to operate. It prints
19 out the material safety data sheets.

20 DR. GALSON: No. I'm saying that Rite-Aid
21 doesn't talk to CVS, doesn't talk to --

22 DR. MAY: Oh, they talk through the NACDS,
23 which is the National Association of Chain Drugstores.

24 DR. GALSON: The computer systems aren't

1 linked.

2 DR. MAY: Oh, right. No, their computer
3 systems aren't linked chain-to-chain, no.

4 DR. GALSON: Okay. The other question is,
5 does NABP believe that counseling should only be given
6 to the drug prescribed or should a pharmacist question
7 the individual on what other drugs they're taking and
8 provide counseling? I think you really answered that
9 already.

10 DR. MAY: Well, let me just add one thing.
11 That is done by the fact that in a chain particularly,
12 knows all the drugs being taken. They see that a
13 certain drug may be contraindicated because they go to
14 multiple physicians for one. Everybody doesn't go to
15 the same cardiologist that go to a GP that go to a
16 dermatologist.

17 There are already prescriptions. They're all
18 getting filled by, say, Giant because they're loyal to
19 that. That will become known to the pharmacist, that
20 they're getting this drug, this drug and this drug, and
21 there are one or two or three contraindications, so
22 they shouldn't be taking it.

23 They will then call the doctor and say are
24 you aware that Dr. So and So is prescribing this? Oh,

1 my God, no. Got to get him off of that, and there is
2 an interaction to stop that from happening. It's on-
3 going. It's very effective. It should be increased in
4 all pharmacies but yes, that is happening.

5 So, including the inclusion of over-the-
6 counter drugs because they ask the patient, when they
7 get them as a new customer, what other drugs are you
8 taking by prescription, what other drugs are you taking
9 over-the-counter. They give them a sheet of paper.
10 They fill it out and that data is entered into that
11 company's computer, and all of that's in there.
12 They're taking these over-the-counter.

13 Now, the patient can say oh, I don't want him
14 to know what I'm taking over-the-counter because the
15 doctor may not know all of them, but it's asked by
16 chains. It's asked by pharmacies and that data is
17 entered into the computer system, and it's all there,
18 including software that has warnings for overdoses,
19 warnings for drugs that are contraindicated and
20 interact with each other. They get a message coming
21 out. These drugs should not be taken together. They
22 then call the doctor, call the patient. All those
23 things are in play today.

24 DR. GALSON: Okay. If there's time, I'll

1 read the statement quickly. There is a drug
2 recognition officer in the audience, and he wanted
3 folks to know that in the program, most states use
4 urine, not blood. Only nine states have a blood
5 demand, and the DRE determines the impairment. The
6 body fluid confirms the drug.

7 DR. ELLINGSTAD: Okay. Thank you, everyone.
8 We're right on schedule again.

9 What we'll do now is take about a five-minute
10 stand-up and stretch break in order to switch our
11 panels. I'd like to remind all of the witnesses who
12 have presented that we -- if they have not turned in
13 the copies of their presentation, we need them, and if
14 they'll check with the people at the desk out in the
15 lobby, we'll collect that.

16 Thank you.

17 (Pause)

18 DR. GALSON: Okay. I think we're ready for
19 our last panel for the day, our fourth panel, Members
20 from the Military, and I want to welcome Colonel
21 Saenger and Captain Fulton, respectively, from the Air
22 Force and the Navy.

23 We've been starting from the right side. So,
24 Captain Fulton, if you want to start first.

1 Witness Panel IV - Military

2 CAPTAIN FULTON: Thank you.

3 Good afternoon, and I guess it's almost
4 evening. But I'm Captain Dwight Fulton. I'm the
5 Director of Aerospace Medicine for the United States
6 Navy.

7 As such, I am the medical representative for
8 really only one of the operational arms of the U.S.
9 Navy and am best able to focus my comments therefore on
10 how we in naval aviation address the issues outlined in
11 the goals for this particular meeting, those goals
12 being essentially data available to define the role of
13 impairing medications in accidents and related issues,
14 how the potential for medications to cause impairment
15 might be best assessed, and then how this risk would be
16 most effectively communicated to the public or, in this
17 case, to our naval air crew.

18 As relates to data available to define the
19 role of impairing medications in accidents and related
20 issues, accidents involving naval aircraft trigger a
21 safety investigation. It is conducted by our Aviation
22 Mishap Board, made up of personnel from within the
23 mishap squadron and from without.

24 Included in these investigations is the

1 flight surgeon assigned to that specific squadron. The
2 flight surgeon's responsibility is to identify any
3 medical or human factors that may have been causative
4 factors contributing to that particular mishap.

5 Part of the flight surgeon's responsibility
6 is to conduct drug testing for prescribed narcotics or
7 other non-prescribed illicit medications, to conduct a
8 review of any involved air crew medical records, to
9 obtain 72-hour histories on all involved air crew, and
10 to conduct a physical exam on any of the air crew that
11 were involved in that mishap.

12 If, in the course of this work-up, it is
13 found that the air crew was on any medications, it is
14 also that flight surgeon's responsibility to determine
15 if the side effects or the therapeutic effects of these
16 medications could have contributed to that specific
17 mishap.

18 As an aside, in many of our operational
19 sites, the cognizant medical treatment facility
20 completes an accident report on anyone who presents
21 with injuries related to a specific accident. These
22 reports are usually maintained locally, unless the
23 accident exceeds an indicated number of lost work days,
24 and then the report gets submitted up the chain of

1 command to the Naval Safety Center. Therefore, the
2 Naval Safety Center is a repository for some limited
3 number of accidents that meet specific criteria.

4 These non-standardized accident reports
5 generated on the local level will usually ask for any
6 medications that the person involved in the accident
7 may have been taking.

8 As relates to how the potential for
9 medications to cause impairment might be best assessed,
10 in naval aviation, there is no physical testing process
11 in place to assess the potential for medications to
12 cause impairment in air crew. There was some work done
13 at the Naval Aeromedical Research Lab in Pensacola,
14 Florida, in past years, looking at establishing a
15 battery of tests to assess the cognitive effects of
16 different medications recommended for naval aviation,
17 but to date, no specific battery of tests has been
18 approved.

19 Currently, medications that are considered
20 for use in naval aviation are reviewed by the
21 Aeromedical Advisory Council at the Naval Aerospace
22 Medical Institute in Pensacola, Florida. Information
23 considered in this review process includes any recent
24 medical literature and science regarding the potential

1 side effects of the proposed medication, the known uses
2 of the proposed medications in the civilian and
3 military communities, and the current stand of our
4 sister services on these particular medications.

5 As relates to how this risk would be most
6 effectively communicated to the public, and in this
7 case, our public is naval air crew, in naval aviation,
8 it's our flight surgeons and our aviation technicians
9 who are messengers out there in the fleet.

10 The flight surgeons are trained on the
11 medications that are compatible with naval aviation and
12 are responsible for monitoring their air crew to ensure
13 that there is no use of undesignated medications. They
14 do this through spending time with the air crew in
15 their spaces and through annual assessment of an air
16 crew's medical history and physical status.

17 During these annual assessments of
18 medications, air crew are reminded that they are not to
19 use any medications without the flight surgeon's
20 consent.

21 In addition, a pilot is reminded that if he
22 is seen by a physician other than a flight surgeon, he
23 is grounded until a flight surgeon has reviewed the
24 medical care and treatment provided by that other

1 physician.

2 In addition, the flight surgeon conducts
3 safety briefs in the squadron spaces, and the issue of
4 medications is one of those issues that's briefed on a
5 regular basis.

6 This naval policy on medication and air crew
7 is further reinforced by our line community in our
8 OPNAV Instruction 3710.7R, which is the Guidance on
9 General Aviation Policy. This guidance reinforces that
10 an air crew man should not take any medications, over-
11 the-counter or otherwise, without the explicit approval
12 and supervision by the flight surgeon.

13 Again, I'm not really astutely aware of how
14 medication is used, use is monitored and controlled
15 with other forms of transportation than the Navy, but I
16 would be glad to research and provide any information
17 to you on these specific areas, if requested.

18 DR. GALSON: Thank you very much.

19 The next speaker is Colonel Arleen Saenger
20 from the Air Force.

21 COLONEL SAENGER: Good afternoon.

22 I'm Arleen Saenger. I'm the Chief of
23 Aerospace Medicine in the Air Force Office of the
24 Surgeon General. As such, I am analogous to Dwight and

1 that of the Director of the Aerospace Medicine Program
2 for the Air Force.

3 Our programs regarding aviators are very much
4 analogous and essentially the same as they are for the
5 Navy. So, I'll touch briefly on that, but I'll also
6 touch a bit on what ground safety data I was able to
7 get from our Air Force Safety Center.

8 I'm going to address the two specific key
9 questions. How has the U.S. Air Force addressed the
10 use of medication by transportation operators, and how
11 effective have our efforts been?

12 Additionally, what is our experience in
13 assessing, communicating and preventing the risk of
14 sedating or impairing medications in vehicle operators,
15 and how are our applicable laws or what we would call
16 instructions or regulations enforced?

17 First, aviation and then ground. As I said,
18 the mishap investigation for aviation mishaps is
19 essentially the same for the Air Force as it is for the
20 Navy. So, I won't go into that in any detail.

21 Our Air Force Instruction on Medical
22 Standards specifically addresses the use of
23 medications, both prescription and over-the-counter, by
24 air crew and what we call special duty personnel. For

1 instance, air traffic controllers and others.

2 Medications are not allowed to be taken
3 without the specific permission of the flight surgeon,
4 just like for the Navy. There are certain medications
5 which we can waiver for our air crew use which the
6 local flight surgeon can allow the air crew to use once
7 a period has passed so he can determine there's no
8 adverse side effects. There are other medications
9 where you have to request formal waiver from higher
10 Headquarters.

11 In no case is the aviator allowed to perform
12 flight duties while taking a medication that would be
13 sedating or impairing.

14 Medications that are sedating or impairing
15 result in a grounding, a temporary grounding or NIF
16 duties, not to include flying action, and the aviator
17 cannot go back to flying duties until cleared by the
18 flight surgeon.

19 As with the Navy, we also require the flyer
20 to report to the flight surgeon's office after being
21 seen by any provider outside of the flight surgeon's
22 office. They are to consider themselves grounded until
23 otherwise cleared by the flight surgeon.

24 As for education on the use of medications,

1 like the Navy, this is a frequent briefing topic with
2 our aviators. We drill it into their heads at every
3 opportunity. It's a mandatory briefing item at
4 squadron safety meetings. It is discussed in
5 encounters in the squadron informally. It's discussed
6 in the encounters in the flight surgeon's office, both
7 by the doctor and by the technicians, the aeromedical
8 technicians. So, we educate, educate, educate.

9 We feel it's been very effective in our Air
10 Force aviator population. There have been no mishaps,
11 aircraft mishaps in the Air Force where the use of
12 medication, prescription, over-the-counter, licit,
13 illicit or otherwise, has been found contributory.

14 How do we enforce it? Again through mostly
15 education. We know our population. We have a very
16 defined population that we see on a daily basis. We
17 know them. We know their families. We know the
18 squadron, and education is a key to that.

19 The commander can take administrative action
20 if anybody is found to be self-medicating without
21 reporting to the flight surgeon. I don't have any data
22 on how often that has ever happened, though.

23 Mishap data. We do toxicologic testing on
24 all aircraft mishaps, regardless of cost, in terms of

1 cost of the mishap, that is. We do screen for carbon
2 monoxide, ethanol, amphetamines, barbiturates,
3 benzodiazepines, cocaine, opiates and bencyclidine. We
4 also screen for various typical over-the-counter and
5 prescription medications, too, on a varying basis.

6 Ground mishaps are a different issue. We've
7 got a fairly robust database for aviation mishaps, but
8 for ground mishaps, it is a different issue, as was
9 noted in the NTSB Board recommendations from January of
10 2000.

11 There is a manual that addresses wheeled
12 vehicle drivers. It's an Army field manual and an Air
13 Force joint manual. That is the only regulation or
14 instruction that we have that governs wheeled vehicle
15 drivers, and the only note in that instruction is a
16 note to a table where it states, "The driver is
17 responsible for notifying your supervisor or NCO of any
18 change in your status; for example, inability to drive
19 due to a physical condition." So, we really don't have
20 any regulations or rules, other than that, governing
21 medication use by ground vehicle operators.

22 Education is problematic, also. There is no
23 systematic education for ground vehicle operators. We
24 rely solely upon the medical provider and the

1 pharmacist in educating the patient on the side effects
2 of the medication that they're being prescribed or that
3 they might be buying over-the-counter.

4 How effective is very difficult to determine
5 due to the policy issues of not having any rules
6 governing it and relying solely on provider and
7 pharmacist education but also on database issues.

8 Currently, the Air Force collects data on
9 ground vehicle mishaps only for Class A mishaps, and
10 those are mishaps which involve a total cost of a
11 million dollars or more, a fatality or a permanent
12 total disability.

13 The database that we do have has a very
14 limited search capability. Nonetheless, the Safety
15 Center did a review of about 12 years of motor vehicle
16 Class A mishaps. Almost all of these involved
17 fatalities. Of 986 Class A mishaps during that time,
18 there were only two in which drug use was found to be
19 contributory. One was for cannabis and one was for
20 cocaine. However, this is not complete data.

21 Testing is not required. In fact, in only 55
22 percent of these cases was testing done on the involved
23 driver. Testing is only required if, in the opinion of
24 the police officer on the scene, is necessary or if the

1 member's commander directs it.

2 Enforcement's also problematic, unless there
3 is some legal military action to be taken on the part
4 of the commander, and we have no data regarding numbers
5 or anything of that nature.

6 For our future directions, the Safety Center
7 has recognized there's a very large knowledge gap here,
8 and we are developing a program to require human
9 factors investigation on all mishaps, air and ground,
10 all classes, all cost classes. So, everything ranging
11 from a \$2,000 mishap with a minor injury all the way up
12 to a million dollar mishap or loss of life, air or
13 ground, will have human factors investigation, and as
14 part of that, it will include drug testing, but that's
15 being developed currently.

16 There will be a database that will go along
17 with that, the information systems, to support that,
18 but it's a future thing. Right now, we don't have a
19 very good ground mishap reporting data collection
20 system.

21 That's it for the Air Force. Glad to take
22 any questions.

23 DR. GALSON: Great. Thanks very much.

24 We're going to first start with questions

1 from the Technical Panel, and Dr. Andreason, do you
2 want to start?

3 Questions from Technical Panel/Parties and Discussion

4 DR. ANDREASON: Sure. Thank you very much
5 for your presentations.

6 First of all, I just wanted to say that my
7 dad was an Air Force officer in a fighter squadron.
8 So, some of my questions will be based on his
9 experience.

10 It's my understanding that you do have a list
11 of acceptable drugs for flight crew. How did that
12 list come about?

13 COLONEL SAENGER: It's evolved over the
14 years. It also has evolved somewhat as the Navy has,
15 where we get consultant input. We pull the other
16 services, our sister services in the U.S. and also our
17 allied services for their experience with the
18 medication. Literature research. But a lot of it is
19 simply based on a body of usage, and those drugs are
20 specifically listed in our Air Force Instruction
21 48.123, which is Medical Standards.

22 DR. ANDREASON: So, you have a review board
23 that kind of reviews these as they come out, is that
24 correct?

1 COLONEL SAENGER: Not as the drug comes out,
2 no, but if somebody in the field raises the issue or if
3 one of the major command flight surgeons raises the
4 issue of this might be something we'd want to consider
5 allowing for use in air crew, then the background
6 research and the decision process starts.

7 We have an Aerospace Medicine Corporate
8 Board, which is composed of all the flight surgeons,
9 the command flight surgeons for the various Air Force
10 major commands, along with individuals from the
11 Aeromedical Consult Service at Brooks Air Force Base
12 and the School of Aerospace Medicine at Brooks Air
13 Force Base, and it becomes a joint decision, based on
14 research, and sometimes it's just gestalt.

15 DR. ANDREASON: Well, that pretty much
16 answers my question, but maybe to beat the horse a bit
17 more. Could you perhaps take me through some
18 hypothetical steps about how, say, a new ostensibly
19 non-sedating antihistamine might make it on to this
20 list?

21 COLONEL SAENGER: That was done specifically
22 with a literature review, an extensive literature
23 review. Part of the problem with literature review is
24 we're concerned with some neuropsychiatric side effects

1 and some subtle impairing side effects that are not
2 necessarily addressed during the testing for the FDA
3 for approval to use it.

4 So, it's extensive literature review and
5 consultants, specialty consultants, subject matter
6 experts. We gather their inputs, and we go over the
7 results of that and debate it a lot, and then we come
8 to a thumbs-up/thumbs-down decision and take a vote.

9 DR. ANDREASON: So, now in the United States,
10 because of the user fee initiative, drugs are often
11 released first in the United States instead of other
12 countries. There's not a lot of data outside of what's
13 in the labeling.

14 Does that mean that, say, a new antihistamine
15 might not make it on to the flight crew list until this
16 type of research was done in the academic community or,
17 say, as part of a Phase IV commitment?

18 COLONEL SAENGER: Yes. We wouldn't jump on
19 something the day it was released. We would want to
20 see at least a year or preferably more of post-
21 marketing data that we could look at.

22 CAPTAIN FULTON: One other thing to comment
23 on, too, is that when a medical -- usually or at least
24 in terms with the Navy, when we start a particular

1 medication or introduce a new medication, it's a
2 gradual process to bring the medication on.

3 A lot of times, we just don't bring it on and
4 then, okay, you can start using this medication carte
5 blanche. What we do is we waiver some of our
6 individuals to be on these medications for a particular
7 period of time. By being on a waiver, then they're
8 closely -- more closely monitored by the flight
9 surgeons than a drug that was not considered
10 disqualifying and could be used on a regular basis.

11 So, they'll watch for a period of time, and
12 then, after they've -- that medication, we see in the
13 air crew that it hasn't caused any significant
14 impairment or side effects, then that drug will be
15 upgraded to a not-considered-disqualifying drug, and
16 those individuals can then use it without having a
17 waiver, as long as it's prescribed by a flight surgeon.

18 COLONEL SAENGER: It's very much like that in
19 the Air Force, too.

20 Another thing that we do, I believe, that
21 Navy does, also, is we'll start with the back-end, so
22 to speak, of the aircraft and move forward, and we may
23 allow a medication used with or without a waiver, but
24 with a waiver usually, for a load master or an air

1 battle manager, and then, after we gain experience with
2 it at that level, approve it for use in our aviators.

3 DR. TEMPLE: These things are done
4 systematically? There'll be a servicewide decision
5 that the flight surgeon can allow use of something, so
6 everybody will know about it, and do you record the
7 results?

8 COLONEL SAENGER: Yes, there is.

9 DR. TEMPLE: It's not just local option?

10 COLONEL SAENGER: No. No, it's not just
11 local option. We'll publish a policy memorandum, and
12 then when it comes time to change the instruction,
13 we'll add it.

14 DR. TEMPLE: And have you sent your lists to
15 us, and can you?

16 COLONEL SAENGER: Yes, I can.

17 DR. GALSON: Let me just exercise the
18 prerogative of the chair here and ask you, what's the
19 status of the sedating antihistamines on these lists?

20 COLONEL SAENGER: We allow non-sedating with
21 waiver.

22 DR. GALSON: Sedating?

23 COLONEL SAENGER: No.

24 DR. GALSON: Under no circumstances?

1 COLONEL SAENGER: Under no circumstances.

2 DR. GALSON: You wouldn't want to say which
3 or which, would you?

4 COLONEL SAENGER: Allegra and Claritin.

5 DR. GALSON: Okay. Sorry to interrupt there.
6 Please continue with the Technical Panel questions.

7 DR. TEMPLE: I'm sure we'll be interested in
8 the list, and, you know, any other on-the-way things
9 that you're working on. I mean, how to gain
10 information about this sort of thing is part of the
11 problem here. So, how you do it in a relatively
12 controlled environment is going to be very interesting.

13 CAPTAIN FULTON: It's interesting because I
14 just came back from a standardization meeting over in
15 England regarding all of the English-speaking Air
16 Forces. The British were present, the Australians, New
17 Zealand, Canada, and all the services from the United
18 States, and one of the things that -- one of the
19 information-gathering things we're going to be doing
20 over the next year is identifying what the processes
21 are that the different services have to evaluate these
22 medications, and where they're going with these
23 particular processes, because right now, I don't think
24 any of the services, at least based on the meeting that

1 I was at, have a systematic process by which we do
2 testing on the particular medications, tox screens,
3 although I believe that the Air Force has a process
4 that they're working on and to bring into action, and I
5 know that the Navy, like I said in my introductory
6 remarks, looked at a process several years ago, but I
7 think that that kind of died, and there's no process in
8 place right now.

9 COLONEL SAENGER: What I was referring to is
10 a process for doing what we're calling "one of"
11 occupational evaluations. The issue is we don't have
12 the resources to do systematic research, as we did, for
13 instance on my Centapro, in order to determine whether
14 that was allowed in air crew, in pilots, or not.

15 If we've got an aviator whose not had an
16 adequate response to an allowed medication for his or
17 her condition, and you try a medication that's not on
18 the list, and it works really well, how do we assess
19 them for allowing them to have a waiver or not?

20 The proposed process that we have, it's due
21 to start fairly soon now, the Consult Service, I don't
22 believe we've had our first patient down there under
23 this protocol yet, is to bring the individual down off
24 the medication, do the neurocog testing. If they are

1 in fighters, put them in the centrifuge, put them back
2 on the medication for a period over the weekend, retest
3 them because we want to know before and after.

4 It's an N of 1, but for that individual, it's
5 a mechanism for allowing them to fly on that medication
6 that's not currently on the air crew waiver list.

7 DR. ANDREASON: They do that down at Brooks?

8 COLONEL SAENGER: Yes, at the Aeromedical
9 Consult Service, Brooks.

10 DR. ANDREASON: Are there any drugs that are
11 considered impairing that are not necessarily sedating
12 that are not allowed in the Air Force?

13 COLONEL SAENGER: Impairing from a
14 psychological standpoint? Yes. We tend to think of
15 impairing in terms of neurocog, but there is G
16 tolerance issues that we both have to address.

17 DR. ANDREASON: Neurocognitive. That's kind
18 of what we're driving at. So, in that sense, it would
19 be blood loss or blood profusion problems?

20 COLONEL SAENGER: Yes.

21 DR. TEMPLE: Wait a minute. The beta
22 blockers have a number of things they do that might
23 make you think a person couldn't respond to an
24 emergency.

1 Are there any things that affect
2 neurocognitive function that are not sedating that are
3 on your list? I think that's the question. That's
4 what they wanted to know.

5 CAPTAIN FULTON: Without having a list
6 sitting here right in front of me to answer that
7 specific question, I can't.

8 DR. TEMPLE: Okay. You can imagine people
9 would worry about amphetamines, not because they sedate
10 you but because they distort the way you react to
11 things.

12 COLONEL SAENGER: Yes.

13 DR. GALSON: Does NTSB have any questions?

14 DR. GARBER: Yes, and I know this is going to
15 sound strange to my military colleagues to even ask
16 this question, but I assure you that from a civilian
17 perspective, it is meaningful.

18 The military prohibits the use of all
19 medications for their air crew, unless those
20 medications have been specifically evaluated and
21 determined to be safe for their use.

22 Why has the military taken that approach;
23 that is to say, prohibiting everything and allowing
24 only a few things, as opposed to allowing everything,

1 unless it has been proven to be impairing?

2 CAPTAIN FULTON: I'll take a stab at that
3 one, okay, but (1) I think it gives us a little bit
4 tighter control over what medications individuals take,
5 you know, and I think that, you know, if we allowed
6 everything, if we allowed everything, we wouldn't have
7 any control over what medications are taken.

8 DR. GARBER: So, you would be civilians?

9 COLONEL SAENGER: We would be civilians. I
10 suppose it reflects the different philosophies. It's
11 safe until proven unsafe or it's unsafe until proven
12 safe, and if we allowed everything, it would be an
13 issue just the span of control to allow everything and
14 then have to prove specific things on faith in order to
15 disallow them. It would be a lot harder to do than
16 just say no, we're going to disallow everything, and
17 then what we can prove through experience, research,
18 whatever to be safe is more approachable, more
19 obtainable.

20 DR. GARBER: Do you find it odd that a
21 different approach is used in the civilian community?

22 COLONEL SAENGER: No. There's lots of other
23 examples of that, too. Plus, we have a more
24 controllable population. When you know your

1 population, and it's very defined, and you control
2 their medical records, and you see them at the club,
3 and you see them at the commissary, you can -- you have
4 greater span of control and greater span of influence.

5 You're dealing with a totally different population on
6 the civilian side.

7 DR. GARBER: Dr. Temple reminds me that we
8 actually -- that from what you've told us, that the
9 military ground approach is actually very similar to
10 the civilian approach throughout transportation.

11 Is there a reason that the military uses a
12 different approach for their ground personnel than they
13 do for their aviation personnel?

14 COLONEL SAENGER: Well, being the Air Force,
15 we tend to emphasize aviation, which is, you know, the
16 ground is still important. I think it just hasn't been
17 given the attention which is why the Safety Center has
18 brought the issue up through their line channels and
19 through the Air Force Surgeon General saying this is a
20 major safety issue, also, and we need to start
21 attending to and dealing with this.

22 The Army may have some more data on ground,
23 but, unfortunately, he's not here. So.

24 CAPTAIN FULTON: I think one of the other

1 issues to look at, too, is when -- I'm not sure about
2 the Air Force on this, but I know with the Navy, when
3 we have a mishap, we look at all the people that may
4 have been involved in that mishap, okay, and so, you
5 know, for us in a lot of circumstances, that includes
6 ground crews, and that includes the people who are from
7 those areas.

8 So, if there's a mishap investigation done,
9 and we do toxicology evaluation on the pilot, well, we
10 may also do toxicology evaluation on the air crew that
11 worked on that airplane to make sure that that wasn't a
12 causative factor that's involved in that particular
13 mishap, and the other area that concerns us very much
14 in the Navy obviously is the flight decks on aircraft
15 carriers, where we have a large number of people, and
16 as a matter of fact, we're working on the process now
17 and trying to include the process by which we monitor
18 the people that are on the flight deck and what
19 medications those individuals are taking.

20 DR. GARBER: So, I think what I'm hearing is
21 that as with the civilian community, this is an area of
22 emerging concern for the military services?

23 COLONEL SAENGER: And the Air Force does
24 check on aircraft mishaps, if there's a ground